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NATIONAL INSTITUTES OF HEALTH
CONSENSUS DEVELOPMENT CONFERENCE STATEMENT
National Institutes of Health State-of-the-Science Conference:
Role of Active Surveillance in the Management of Men With Localized Prostate Cancer
December 5–7, 2011

National Institutes of Health (NIH) consensus and state-of-the-science statements are prepared by independent panels of health professionals and public representatives on the basis of (1) the results of a systematic literature review prepared under contract with the Agency for Healthcare Research and Quality (AHRQ), (2) presentations by investigators working in areas relevant to the conference questions during a 2-day public session, (3) questions and statements from conference attendees during open discussion periods that are part of the public session, and (4) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of NIH or the Federal Government.

The statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.

Introduction

Prostate cancer is the most common cancer in men. In 2011, more than 240,000 men are projected to be diagnosed with prostate cancer and 33,000 are projected to die from this condition. More than 2.5 million men in the United States are long-term survivors of prostate cancer. Men with a strong family history of prostate cancer and African American men are at increased risk for developing prostate cancer. Most prostate cancer is localized at diagnosis and detected as a result of screening with prostate-specific antigen (PSA) testing (PSA is a protein released by the prostate). Most of these screen-detected prostate cancers are low risk and are unlikely to be the cause of death. The natural history of prostate cancer has changed dramatically in the past three decades because of PSA screening.

Although most prostate cancers are slow growing and unlikely to spread, most men receive immediate treatment with surgery or radiation. These therapeutic strategies are associated with short- and long-term complications, including impotence and urinary incontinence. Only a small number of men choose observational strategies, which may delay the initiation of curative therapy or avoid it completely. Given the high prevalence of low-risk prostate cancer, there is an urgent need to clarify the role of active surveillance and other observational strategies as alternatives to immediate treatment.

To provide health care providers, public health practitioners, policymakers, and the general public with a comprehensive assessment of the current role of active surveillance in management of men with localized prostate cancer, the National Cancer Institute, the Centers for Disease Control and Prevention, and the Office of Medical Applications of Research convened a State-of-the-Science Conference on December 5-7, 2011, to assess the available scientific evidence. The panel was asked to address the following key questions:

1. How have the patient population and the natural history of prostate cancer diagnosed in the United States changed in the last 30 years?

2. How are active surveillance and other observational strategies defined?

3. What factors affect the offer of, acceptance of, and adherence to active surveillance?

4. What are the patient-experienced comparative short- and long-term health outcomes of active surveillance versus immediate treatment with curative intent for localized prostate cancer?

5. What are the research needs regarding active surveillance (or watchful waiting) in localized prostate cancer?

During the first 2 days of the conference, experts presented information on each of the key questions. After weighing the scientific evidence—including the data presented by the speakers, input from the attendees, and a formal evidence report commissioned through the Agency for Healthcare Research and Quality—an independent panel prepared and presented a draft of this State-of-the-Science Statement addressing the conference questions.

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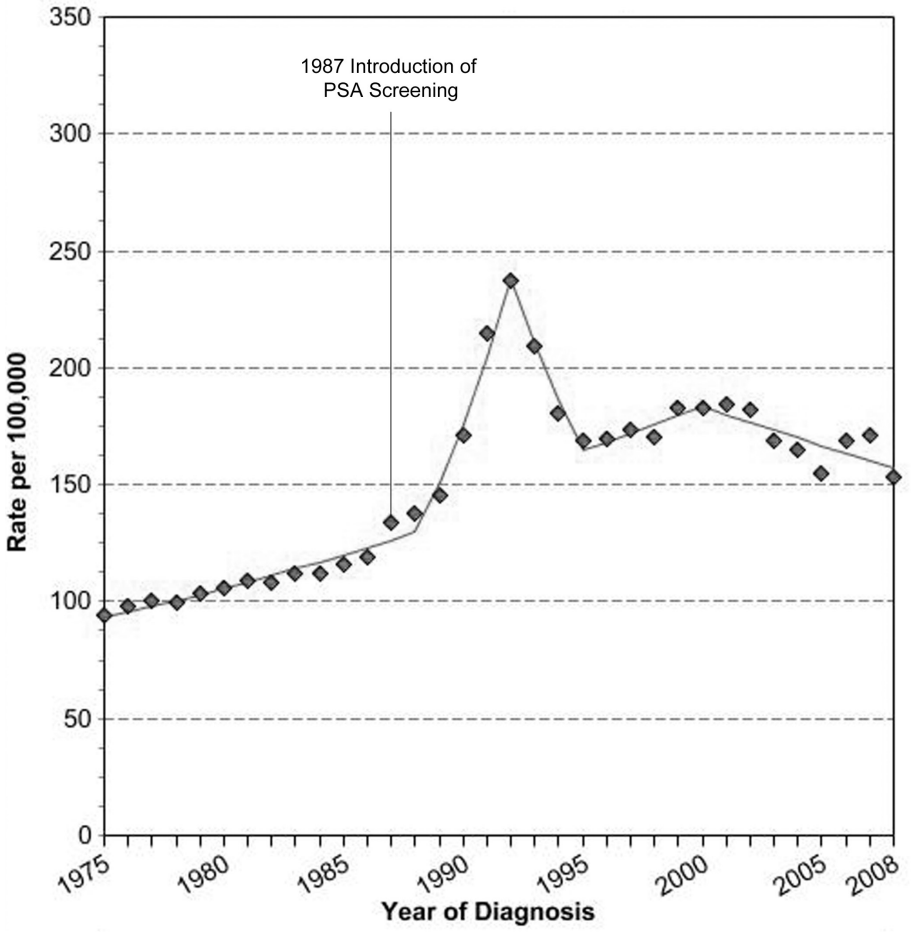
1. How have the patient population and the natural history of prostate cancer diagnosed in the United States changed in the last 30 years?

Prior to the adoption of PSA screening, the majority of prostate cancer was detected because of symptoms of advanced cancer or a nodule found on digital rectal examination. The symptomatic tumors were usually high grade, advanced, and often lethal. Other tumors were found incidentally at the time of surgery for benign enlargement of the prostate. These were often low grade and localized.

After the introduction of PSA screening in 1987, there was a spike in the rate of prostate cancer cases detected, followed by a persistent elevation above the pre-PSA testing era (see Figure 1). The lack of an increase in the rate of prostate cancer deaths suggests that the detected tumors are largely low risk and do not lead to the death of patients. Furthermore, other 20-year follow-up studies indicate that only 5 percent of these men die from prostate cancer.

Figure 1. Prostate Cancer Incidence (1975–2008)



Incidence source: SEER 9 areas (San Francisco, Connecticut, Detroit, Hawaii, Iowa, New Mexico, Seattle, Utah, and Atlanta).

Data obtained from SEER Fast Stats. Last accessed December 6, 2011.

All of these trends led to the need for modifications in the approach to diagnosis and treatment of prostate cancer. Today, most prostate cancer is diagnosed by multiple core needle biopsies, which are graded using a powerful prognostic system called Gleason scoring. In this system, the patterns of arrangement of tumor cells are given a pattern designation from 1 to 5, based on their relationship to normal prostate glands. Pattern 1 is the lowest grade, and pattern 5 is the highest grade. Each tumor is assigned two patterns, one of which is the most frequently seen and the other being the highest grade. The pattern numbers are then added to provide a pathologic diagnosis called the Gleason score. The Gleason scores are relied upon as the most powerful indication of the patient's expected outcome and are commonly used to define treatment strategies. Tumors called Gleason 3+3=6 are the lowest scores usually given in needle biopsy core specimens and are considered the lowest grade. More than 50 percent of all prostate cancers are assigned scores of 6 by pathologists. This scoring method suffers from interobserver variation and from difficulties with sampling as such specimens constitute less than 0.5 percent of biopsy tissue even when multiple cores are sampled.

By 2002, more than 63 percent of all prostate cancers detected in one large series were Gleason 3+3=6. It is likely that the percentage of cases labeled as Gleason score 6 has increased since that time. Gleason score changes parallel the increased number of prostate cancer patients with PSA less than 10ng/ml.

Decisions about prostate cancer treatment depend on accurate pathologic diagnosis. We need to ensure the level of agreement of Gleason scoring among doctors who examine prostate tissue to

have consistent scoring results and to evaluate prostate cancer biomarkers that are different from PSA and are predictive of cancer behavior.

2. How are active surveillance and other observational strategies defined?

There are two observational strategies: active surveillance and watchful waiting. These terms have evolved over time and have not been consistently applied. **Active surveillance is a disease management strategy that delays curative treatment until it is warranted based on defined indicators of disease progression.** In contrast, watchful waiting is a disease management strategy that forgoes curative treatment and initiates intervention only when symptoms arise.

The three components of a given observational management strategy are eligibility criteria, follow-up protocols to monitor disease progression, and indicators for treatment. The evidence report identified 16 studies that meet the definition of active surveillance and another 13 that followed patients who did not receive treatment and were followed for symptom progression (watchful waiting).

Eligibility Criteria

The most widely accepted criterion for active surveillance eligibility is the presence of low-risk clinically localized disease. Tumor characteristics commonly used to identify such low-risk cancers include tumor stage (T1c, PSA detected or T2a, small palpable nodule), PSA level

(less than 10 ng/dL), Gleason score (less than or equal to 6), and extent of disease on biopsy (number of individual core biopsy specimens (cores) with cancer and percentage of each core with cancer). Patient characteristics have been used inconsistently to determine eligibility and include age and overall health status, which are a reflection of life expectancy.

Watchful waiting, which predated active surveillance as an observational strategy, arose out of the recognition that death from other causes exceeded death from prostate cancer in men with shorter life expectancies. Thus, watchful waiting studies used less rigid eligibility criteria, accommodating men who were older, who had more chronic illnesses, or who preferred less invasive treatment. These criteria, while similar to those used in active surveillance, allow higher PSA levels and higher clinical stage in the absence of metastatic disease.

Follow-up Protocols

The purpose of the active surveillance follow-up protocol is to detect disease progression. In previous studies, follow-up parameters included PSA, digital rectal exam, and rebiopsy. PSA and digital rectal exam were variably assessed every 3 to 12 months, but no consensus exists as to the optimal schedule. Repeat biopsy is included in all U.S. studies of active surveillance in order to detect disease progression and misclassification of the original biopsy. The frequency of rebiopsy ranges from one to four procedures, repeated over an initial 4-year period.

The intent of follow-up strategies differs between active surveillance and watchful waiting. In watchful waiting, intervention is reserved for relief of symptomatic disease progression. Studies have monitored PSA at 3- to 6-month intervals.

Indicators for Treatment

Indicators of disease progression that would lead to the recommendation for curative treatment under active surveillance include increased Gleason score on rebiopsy (e.g., presence of Gleason greater than or equal to 7) and faster PSA doubling time (e.g., less than 3 years). Another indicator for curative treatment is increased extent of disease on biopsy. Men may opt to undergo curative treatment at any time; no studies formally define or measure patient behavioral factors or preferences leading to abandoning active surveillance for curative treatment.

Development of symptoms (for example, urinary obstruction, pain, or bony fractures) is the primary indication for treatment under watchful waiting.

Nomenclature

Two broad categories, such as active surveillance and watchful waiting, may be appropriate to address differences in observational strategies and goals. However, as the methods are further developed and refined, new terminology may be needed to distinguish consensus-based methods from historical definitions and to offer patients an appropriate strategy.

Eligibility

Tumor characteristics derived from the prostate biopsy have been the mainstay to determine eligibility for active surveillance of men with low and very low risk tumors. The minimum number of biopsy cores required for representative sampling of the prostate and the value of normalizing PSA values to prostate volume need clarification. Alternatives to Gleason scoring are needed to best identify candidates for active surveillance, to avoid sampling error, and to reduce misclassification of tumors.

Patient characteristics should be measured with standardized self-report instruments and integrated into eligibility decisionmaking. Such characteristics include attitudes and preferences with regard to general and disease-specific quality of life, life expectancy, and anxiety about cancer diagnosis.

Follow-up Protocol

Follow-up under active surveillance is not currently evidence based. The types of monitoring and their optimal frequency need to be defined. It is important to consider whether follow-up should vary based on tumor and patient characteristics. Alternatives to repeat biopsy should be investigated to reduce morbidity and to encourage compliance with active surveillance. However, such new technologies must balance cost and burden to the patient. Follow-up also should monitor ongoing patient concerns with risks of complications, anxiety, and worry about progression.

Predicting whether a particular individual's cancer will progress is difficult. The only clear current indicator of disease progression is an increase in Gleason score. The value of PSA doubling time is uncertain. New indicators of disease progression are needed, such as magnetic resonance imaging (MRI) to identify clinical significant tumors, molecular classification of cancers, and genetic classification of a patient's risk for progression.

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3. What factors affect the offer of, acceptance of, and adherence to active surveillance?

Active surveillance is underutilized as a treatment strategy for men with low-risk prostate cancer, for reasons that are not fully understood. Studies addressing the offer of, acceptance of, and adherence to active surveillance have important limitations. Many studies are small, are unlikely to be representative, and evaluate a limited number of societal and individual factors. These limitations make it difficult to draw clear inferences, but the available data suggest the following:

Offer of Active Surveillance

Observational strategies are not consistently discussed as a treatment option for localized prostate cancer. When active surveillance is included as a treatment option, it may be presented in a negative way—e.g., characterizing an observational approach as "doing nothing." Unfavorable presentations of active surveillance may reflect physician opinion, but also may be an unintended consequence of a specialist's perspective and training. Clinical factors influence

the offer of observational treatment. Physicians are more likely to recommend an observational strategy for men with low-risk disease (low Gleason Score, PSA, and stage), and limited life expectancy.

Acceptance of Active Surveillance

Approximately 10 percent of men who are eligible for observational strategies choose this approach. Perhaps the most critical reason for acceptance is physician recommendation. Other reasons include patients' perception that their cancer is not serious and their concern about treatment side effects. Support from family and friends as well as personal experience with cancer are also important. Patients' decisions also are influenced by information from promotional materials, the Internet, other media, and family and friends.

Adherence to Active Surveillance

Approximately a quarter of patients embarking on observational treatment will undergo curative therapy within 2 to 3 years of diagnosis, and as many as half by 5 years. The reasons for leaving active surveillance are often unclear. Different active surveillance protocols specify various indicators for moving to curative treatment, including increases in PSA and reclassification based on repeat biopsy. In addition, patients often choose to move to active treatment for reasons other than disease progression. Because patients need to reaffirm their commitment to active surveillance on a recurring basis, ongoing physician and family support are important.

The same factors that contributed to the acceptance of active surveillance also may influence adherence.

Future studies of active surveillance would benefit from a robust conceptual framework that better explains the many influences on decisionmaking. Research should explore physician, patient, health system, communications, and other societal factors that influence decisionmaking, and the ways in which these factors interact. Examples include:

- Methods to improve physician counseling about active surveillance
- Methods to improve patient satisfaction and reduce regret in decisionmaking
- Methods to support shared decisionmaking, including non-physician health care providers and the use of decision support tools
- Reasons that patients leave active surveillance
- The effect of emotions (e.g., anxiety) and perceptions about having "cancer"
- Coping factors and the role of the patient's partner, family, and friends
- The impact and timing of communicating an observational strategy as an active care plan

- The role of the media, the Internet, and other communication sources in shaping views about active surveillance

- The impact of race, ethnicity, social class, and access to care in shaping views and decisions about active surveillance.

Ideally, future research also should include comparisons of different strategies for offering and supporting continued participation in active surveillance.

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4. What are the patient-experienced comparative short- and long-term health outcomes of active surveillance versus immediate treatment with curative intent for localized prostate cancer?

There are no randomized clinical trials to determine whether patients who undergo active surveillance have better or worse outcomes than those who receive immediate curative treatment. However, there are cohort studies that are examining active surveillance in men with low-risk disease. Early results demonstrate disease-free and survival rates that compare favorably to curative therapy. There is no standardized reporting of complications associated with the active surveillance strategy in any of the studies reviewed.

The Scandinavian Prostate Cancer Group 4 Trial (SPCG-4) reported a significantly higher prostate cancer-specific mortality and overall mortality rates in patients who were randomized to

watchful waiting compared to radical prostatectomy. These patients were enrolled in the pre-PSA era and had more clinically advanced disease than is seen today. These results may not apply to current populations who are identified with lower-stage disease by PSA screening. There is weak evidence from cohort studies that observational strategies result in an increase in death rates relative to both radiation therapy and radical prostatectomy.

The Prostate Cancer Intervention Versus Observation Trial (PIVOT), a randomized controlled trial that includes a large proportion of patients identified by PSA screening, compared watchful waiting with radical prostatectomy. With a median follow-up of 10 years, there were no statistically significant differences in prostate cancer mortality or all-cause mortality. This trial has yet to be published, and another large trial is under way in the United Kingdom. Supporting data from additional cohort studies give us confidence that the risk of death is minimal in a low-risk population.

There are side effects associated with any treatment strategy for prostate cancer. Radical prostatectomy causes erectile dysfunction and urinary leakage in a substantial proportion of patients. The 30-day mortality of radical prostatectomy is one-half percent. Radiation therapy sometimes causes proctitis, erectile dysfunction, or voiding dysfunction. Active surveillance complications include biopsy-related infections, pain, and anxiety. Rates of these or other complications were not reported systematically. Only those patients who require curative therapy may experience side effects related to radical prostatectomy or radiation therapy, enabling a substantial number of patients who adopt active surveillance to avoid or delay these side effects.

There is limited evidence to determine the short-term impact of active surveillance, relative to immediate treatment strategies, on general health-related quality of life measures such as physical functioning, mental health, social interactions, and role performance. There is some evidence that, for all strategies, physical and mental health recover similarly in the long term. For disease-specific quality of life, both radical prostatectomy and radiation therapy patients experience worse urinary and sexual functioning in comparison to observation patients. These differences persist over time.

Despite the insufficient evidence to determine the outcomes associated with active surveillance compared to other immediate treatment options for prostate cancer, we do not believe randomized clinical trials are necessary to define this for all populations. Given that there are insignificant mortality differences between observational strategies and immediate curative treatment for men with low-risk prostate cancer, the focus of what we still need to learn about active surveillance strategies in this population should be on the impact of treatment morbidity and health-related quality of life. We have a particular concern with the complications that result from image-guided trans-rectal biopsies of the prostate. Standardized protocols need to be developed to minimize frequency and intervals of biopsies and to reduce pain and infection rates. Furthermore, in all future studies, patients' self-report of health-related quality of life indicators both for generic and disease-specific measures are warranted. Costs of these strategies should be measured prospectively, including costs that accrue to patients.

Additional data are still needed to determine how all outcomes—including mortality, morbidity, and health-related quality of life—and costs differ between observational and curative treatment strategies for men with intermediate- to high-risk prostate cancer. Given the variation in how observational strategies have been implemented, we also need to know how active surveillance impacts outcomes relative to other observational strategies.

Future Research Needs

For low-risk prostate cancer patients with a life expectancy less than 20 years, the prostate cancer mortality is so low that we do not recommend a randomized clinical trial comparing an observational approach to immediate treatment with curative intent. For low-risk patients with a life expectancy of more than 20 years, observational strategies could be compared in a randomized clinical trial to immediate treatments with curative intent. For low-risk patients with a life expectancy of less than 20 years, randomized clinical trials comparing health-related quality of life in different versions of observational strategies, including active surveillance, should be performed. Active surveillance and other observational strategies might be compared in randomized clinical trials to intermediate therapy for immediate-risk and high-risk patients.

Randomized clinical trials and cohort studies need to be conducted in cooperative groups, and Federal funding should not be allowed for single institutional trials. Sample size should be large enough in these trials to conduct thorough predetermined subgroup analyses, particularly around the combination of age and risk.

5. What are the research needs regarding active surveillance (or watchful waiting) in localized prostate cancer?

In summary, we have identified the following major areas as critical in the advancement of our understanding of active surveillance in the management of men with localized prostate cancer:

1. Develop or improve pathologic, molecular, and imaging predictive markers, and evaluate their validity and reliability.

2. Examine the differential impact of socioeconomic status, race/ethnicity, and other social determinants on the offer of, acceptance of, and adherence to active surveillance and their effect on morbidity and mortality; and address any disparities emerging from these differences.

3. Determine optimal protocols for active surveillance that minimize the frequency and intensity of monitoring needed to identify disease progression.

4. Develop methods to enhance the decisionmaking process, including physician, patient, health system, communications, and other societal factors that influence patient choices, and the ways in which they interact.

5. Compare the effectiveness of different observational strategies in studies of short- and long-term outcomes. Trials should ideally be done in cooperative or multicenter group settings and should include a variety of populations eligible for active surveillance.

6. Investigate the comparative effectiveness of observational management versus curative therapy for low-risk patients with long life expectancy and for intermediate- and high-risk patients with limited life expectancy.

7. Create registry-based cohort studies that collect longitudinal data on active surveillance participants, including clinical and patient-reported outcomes.

Conclusions

Prostate cancer screening with PSA testing has identified many men with low-risk disease. Because of the very favorable prognosis of low-risk prostate cancer, strong consideration should be given to removing the anxiety-provoking term "cancer" for this condition. Treatment of low-risk prostate cancer patients with radical prostatectomy or radiation therapy leads to side effects such as impotence and incontinence. Active surveillance has emerged as a viable option that should be offered to low-risk patients. However, there are many unanswered questions about active surveillance strategies and prostate cancer. These include:

- Consensus on the best candidates for active surveillance

- The optimal protocol for active surveillance and the potential for individualization based on clinical or patient-related factors

- Optimal ways to communicate the option of active surveillance to patients

- Methods to assist patient decisionmaking

- Reasons for acceptance or rejection of active surveillance as a treatment strategy

- Short- and long-term outcomes of active surveillance.

Well-designed studies to address these questions and others raised in this report represent an important health research priority. Qualitative, observational, and interventional research designs are needed. Due to the paucity of evidence about this important public health problem, all patients being considered for active surveillance should be offered participation in multicenter research studies.

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Planning Committee members provided their input at a meeting held on August 11–13, 2010. The information provided here was accurate at the time of that meeting.

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